

AMENDMENTS TO THE CLAIMS

Claims 1-10 (Canceled)

11. (Currently amended) The method of claim 16, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the amount of BAG-1 protein product using an immunoassay.

12. (Original) The method of claim 11, wherein said immunoassay is an immuno-polymerase chain reaction (immuno-PCR) assay.

Claims 13-15 (Canceled)

16. (Currently amended) A method for prognosis of disease-free or overall survival of an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a sample of said tumor or tumor cells from a body fluid during stage I of said cancer in which the cancer is infiltrating but has no lymph node involvement, wherein a high level of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression correlates positively with disease-free or overall survival.

Claims 17-21 (Canceled)

22. (Currently amended) The method of claim 16 [[21]], wherein said reference level of BAG-1 expression is determined by a histogram analysis.

23. (Currently amended) The method of claim 16 [[21]], wherein said reference level of BAG-1 expression is determined relative to a level of BAG-1 expression produced by *in vitro* cultured cells which produce BAG-1.

24. (Currently amended) The method of claim 16 [[21]], wherein said reference level of BAG-1 expression is determined relative to a level of BAG-1 expression in non-cancerous cells.

25. (Currently amended) A method for predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a sample of said tumor or breast tumor cells from a body fluid from said individual during stage I of said cancer in which the

cancer is infiltrating but has no lymph node involvement, wherein a high level of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression correlates negatively with tumor recurrence or spread.

26. (Currently amended) The method of claim 25, further comprising:

(a) determining an overproduction level for cytosolic BAG-1 protein, said level being in excess of a minimum amount statistically determined to be indicative of decreased likelihood of tumor recurrence or spread;

(b) determining the level of cytosolic BAG-1 protein expression in said tumor sample;
and

(c) predicting said risk of tumor recurrence or spread wherein an overproduction level of cytosolic BAG-1 protein in the tumor sample is negatively associated with the likelihood of tumor recurrence or spread.

27. (Currently amended) A method for screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of cytosolic BAG-1 protein in a cancerous tissue sample or tumor cells from a body fluid sample from said patient during stage I of said cancer in which the cancer is infiltrating but has no lymph node involvement; and

(b) classifying a patient having high levels of expression of cytosolic BAG-1 protein, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival.

Claims 28-31 (Canceled)

32. (Currently amended) The method of claim 27, wherein the level of expression of cytosolic BAG-1 protein is measured using an immunoassay.

33. (Previously presented) The method of claim 32, wherein said immunoassay is an immuno-polymerase chain reaction assay.

34. (Currently amended) A method for determining the proper course of treatment for a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a cancerous tissue sample or tumor cells from a body fluid from said patient during stage I of said cancer in which the cancer is infiltrating but has no lymph node involvement;

(b) identifying a first group of patients having low levels of cytosolic BAG-1 expression relative to a reference level of cytosolic BAG-1 expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or being more likely to suffer tumor recurrence or spread; and

(c) identifying a second group of patients having high levels of cytosolic BAG-1 expression relative to a reference level of cytosolic BAG-1 expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread.

Claim 35-43 (Canceled)

44. (Currently amended) A method for determining risk of tumor recurrence or spread in a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of cytosolic BAG-1 protein in a cancerous tissue of a patient during stage I of said cancer in which the cancer is infiltrating but has no lymph node involvement; and

(b) classifying said patient as belonging either to a first group of patients having high levels of expression of cytosolic BAG-1 relative to a reference level of cytosolic BAG-1 expression, or a second group of patients having low levels of expression of cytosolic BAG-1 relative to a reference level of BAG-1 expression,

wherein said first group has a lower likelihood of tumor recurrence or spread than said second group, thereby determining a lower risk of tumor recurrence or spread in the first group of patients suffering from breast cancer.

Claims 45 – 49 (Canceled)

50. (Currently amended) The method of claim 16, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

51. (Currently amended) The method of claim 25, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

52. (Currently amended) The method of claim 27, wherein said level of expression of cytosolic BAG-1 protein is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

53. (Currently amended) The method of claim 34, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of breast tumor tissue.

54. (Previously presented) The method of claim 16, wherein said disease-free survival is distant metastasis-free survival.

Claim 55 (Canceled).

56. (Currently amended) The method of claim 16, wherein said level of cytosolic BAG-1 protein expression is determined by immunohistochemistry.

Claim 57 (Canceled).

58. (Currently amended) The method of claim 25, wherein said level of expression of cytosolic BAG-1 protein is determined by immunohistochemistry.

59. (Currently amended) The method of claim 27, wherein said level of cytosolic BAG-1 protein expression is determined by immunohistochemistry.

60. (Currently amended) The method of claim 34, wherein said level of cytosolic BAG-1 protein expression is determined by immunohistochemistry.

61. (Currently amended) The method of claim 44, wherein said level of expression of cytosolic BAG-1 protein is determined by immunohistochemistry.

62. (Currently amended) The method of claim 16, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

63. (Currently amended) The method of claim 25, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

64. (Currently amended) The method of claim 27, wherein said level of expression of cytosolic BAG-1 protein is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

65. (Currently amended) The method of claim 34, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

66. (Currently amended) The method of claim 54, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of BAG-1 protein in a sample of body fluid containing breast cancer cells.

67. (Currently amended) A method for prognosis of disease-free or overall survival of an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a sample of said tumor or tumor cells from a body fluid during stage II of said cancer in which the cancer is infiltrating but has spread no further than the lymph nodes local to breast, wherein a high level of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression correlates positively with disease-free or overall survival.

68. (Currently amended) The method of claim 67, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the amount of BAG-1 protein product using an immunoassay.

69. (Previously presented) The method of claim 68, wherein said immunoassay is an immuno-polymerase chain reaction (immuno-PCR) assay.

Claims 70-72 (Cancelled).

73. (Previously presented) The method of claim 72, wherein said reference level of BAG-1 expression is determined by a histogram analysis.

74. (Currently amended) The method of claim 72, wherein said reference level of cytosolic BAG-1 expression is determined relative to a level of BAG-1 expression produced by *in vitro* cultured cells which produce BAG-1.

75. (Currently amended) The method of claim 72, wherein said reference level of cytosolic BAG-1 expression is determined relative to a level of BAG-1 expression in non-cancerous cells.

76. (Currently amended) A method for predicting the risk of tumor recurrence or spread in an individual having a breast cancer tumor, comprising determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a sample of said tumor or breast tumor cells from a body fluid from said individual during stage II of said cancer in which the cancer is infiltrating but has spread no further than the lymph nodes local to breast, wherein a high level of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression correlates negatively with tumor recurrence or spread.

77. (Currently amended) The method of claim 76, further comprising:

(a) determining an overproduction level for cytosolic BAG-1 protein, said level being in excess of a minimum amount statistically determined to be indicative of decreased likelihood of tumor recurrence or spread;

(b) determining the level of cytosolic BAG-1 protein expression in said tumor sample;
and

(c) predicting said risk of tumor recurrence or spread wherein an overproduction level of cytosolic BAG-1 protein in the tumor sample is negatively associated with the likelihood of tumor recurrence or spread.

78. (Currently amended) A method for screening a breast cancer patient to determine the risk of tumor metastasis or chance of survival, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of cytosolic BAG-1 protein in a cancerous tissue sample or tumor cells from a body fluid sample from said patient during stage II of said cancer in which the cancer is infiltrating but has spread no further than the lymph nodes local to breast; and

(b) classifying a patient having high levels of expression of cytosolic BAG-1 protein, relative to a reference level, as being less likely to suffer tumor metastasis or having an increased chance of survival.

79. (Currently amended) The method of claim 78, wherein the level of expression of cytosolic BAG-1 protein is measured using an immunoassay.

80. (Previously presented) The method of claim 79, wherein said immunoassay is an immuno-polymerase chain reaction assay.

81. (Currently amended) A method for determining the proper course of treatment for a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of cytosolic BAG-1 protein expression in a cancerous tissue sample or tumor cells from a body fluid from said patient during stage II of said cancer in which the cancer is infiltrating but has spread no further than the lymph nodes local to breast;

(b) identifying a first group of patients having low levels of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression, which first group of patients may require treatment proper for patients having a lesser chance of survival or being more likely to suffer tumor recurrence or spread; and

(c) identifying a second group of patients having high levels of cytosolic BAG-1 expression relative to a reference level of BAG-1 expression, which second group of patients may require treatment proper for patients having a greater chance of survival and being less likely to suffer tumor recurrence or spread.

Claim 82 (Cancelled).

83. (Currently amended) A method for determining risk of tumor recurrence or spread in a patient suffering from breast cancer, said method comprising:

(a) determining, using a BAG-1 specific antibody, the level of expression of cytosolic BAG-1 protein in a cancerous tissue of a patient during stage II of said cancer in which the cancer is infiltrating but has spread no further than the lymph nodes local to breast; and

(b) classifying said patient as belonging either to a first group of patients having high levels of expression of cytosolic BAG-1 relative to a reference level of BAG-1 expression, or a second group of patients having low levels of expression of cytosolic BAG-1 relative to a reference level of BAG-1 expression,

wherein said first group has a lower likelihood of tumor recurrence or spread than said second group, thereby determining a lower risk of tumor recurrence or spread in the first group of patients suffering from breast cancer.

84. (Currently amended) The method of claim 67, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of breast tumor tissue.

85. (Previously presented) The method of claim 67, wherein said disease-free survival is distant metastasis-free survival.

86. (Currently amended) The method of claim 67, wherein said level of cytosolic BAG-1 protein expression is determined by immunohistochemistry.

87. (Currently amended) The method of claim 67, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of body fluid containing breast cancer cells.

88. (Currently amended) The method of claim 76, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of breast tumor tissue.

89. (Currently amended) The method of claim 76, wherein said level of expression of cytosolic BAG-1 protein is determined by immunohistochemistry.

90. (Currently amended) The method of claim 76, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of body fluid containing breast cancer cells.

91. (Currently amended) The method of claim 78, wherein said level of BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of breast tumor tissue.

92. (Currently amended) The method of claim 78, wherein said level of expression of cytosolic BAG-1 protein is determined by immunohistochemistry.

93. (Currently amended) The method of claim 78, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of body fluid containing breast cancer cells.

94. (Currently amended) The method of claim 81, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of breast tumor tissue.

95. (Currently amended) The method of claim 81, wherein said level of cytosolic BAG-1 protein expression is determined by immunohistochemistry.

96. (Currently amended) The method of claim 81, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of body fluid containing breast cancer cells.

97. (Currently amended) The method of claim 83, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of breast tumor tissue.

98. (Currently amended) The method of claim 83, wherein said level of expression of cytosolic BAG-1 protein is determined by immunohistochemistry.

99. (Currently amended) The method of claim 83, wherein said level of cytosolic BAG-1 protein expression is determined by measuring the level of cytosolic BAG-1 protein in a sample of body fluid containing breast cancer cells.

100. (Previously presented) The method of claim 67, wherein said breast cancer has lymph node involvement.

101. (Previously presented) The method of claim 67, wherein said breast cancer has no lymph node involvement.

102. (Previously presented) The method of claim 76, wherein said breast cancer has lymph node involvement.

103. (Previously presented) The method of claim 76, wherein said breast cancer has no lymph node involvement.

104. (Previously presented) The method of claim 78, wherein said breast cancer has lymph node involvement.

105. (Previously presented) The method of claim 78, wherein said breast cancer has no lymph node involvement.

106. (Previously presented) The method of claim 81, wherein said breast cancer has lymph node involvement.

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107. (Previously presented) The method of claim 81, wherein said breast cancer has no lymph node involvement.

108. (Previously presented) The method of claim 83, wherein said breast cancer has lymph node involvement.

109. (Previously presented) The method of claim 83, wherein said breast cancer has no lymph node involvement.